K063535

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510k Summary of Safety and Effectiveness

FEB 26 2007

Submitted by:	Smith & Nephew, Inc. Orthopaedics Division 1450 Brooks Rd. Memphis TN, 38116
Date:	February 13, 2007 (revised)
Contact Person:	Kim Kelly, Manager, Regulatory Affairs Telephone: (901) 399-6566 Fax: (901) 399-1557
Proprietary Name:	CAPTION Applicator
Common Name:	Syringe
Classification Name & Reference:	21 CFR 880.5860, Piston syringe- Class II
Device Product Code & Panel Code:	FMF, General Hospital

Device Description:
CAPTION Applicators consists of two medical syringes, a 12cc syringe and a 1cc syringe, held in parallel alignment in a molded syringe holder. The plungers of the syringes are joined together by a molded link that allows simultaneous actuation of the syringes. The liquids may be applied through either a dual spray or dual cannula tip.

Intended Use:
CAPTION Applicators are intended for the simultaneous application of two non-homogeneous fluids to a treatment site.

Technological Characteristics:
CAPTION Applicators are similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials, and incorporate similar technological characteristics.

Substantial Equivalence Information:
When compared to the predicates listed below, substantial equivalence was based on similarities in design features, overall indications for use, and material composition:

- Micromedics Surgical Sealant Dispenser – K881020
- Baxter Healthcare Duploject – K973510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim P. Kelly
Manager, Regulatory Affairs
Smith & Nephew, Incorporated
1450 Brooks Road
Memphis, Tennessee 38116

FEB 26 2007

Re: K063535
Trade/Device Name: Smith & Nephew CAPTION Applicator
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 21, 2006
Received: November 28, 2006

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

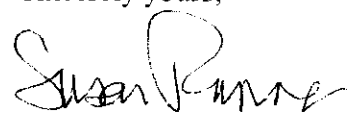
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063535

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: Smith & Nephew CAPTION Applicator

Indications for Use:

For the simultaneous application of two non-homogeneous fluids to a treatment site.

Prescription Use: _____X_____ OR Over-The-Counter _____
(Per 21 CFT 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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